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(54) Method for determining at least one parameter and a breathing apparatus

(57) The present invention relates to a method for determining at least one parameter related to a patient's spontaneous attempts at inspiration and/or the patient's respiratory effort in attempts at spontaneous inspiration. This can be achieved by determining a pressure gradient ($\Delta P/t_m$) in relation to a known apparatus pressure (8) and time (t_m), said pressure gradient ($\Delta P/t_m$) being generated by the patient at inspiration, determining a residual positive pressure (4) in the patient's lungs (Auto-PEEP) and generating an output signal. In principle, the output signal can consist of the determined parameters as well as other related calculated results. For example, the pressure gradient ($\Delta P/t_m$) can be extrapolated against residual positive pressure (4), and both a delay for respiratory assistance and true inspiratory effort can be determined. The invention also relates to a breathing apparatus with which the methods can suitably be performed.

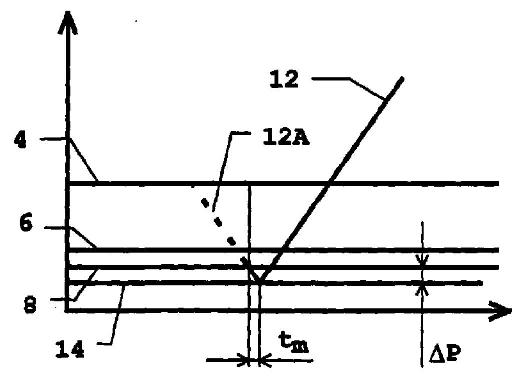

FIG. 2

Description

[0001] The present invention relates to a method according to the preamble to claim 1.

[0002] The present invention also relates to a method according to the preamble to claim 7.

[0003] The present invention also relates to a breathing apparatus according to the preamble to claim 9.

[0004] In normal, spontaneous inhalation, the respiratory musculature creates negative pressure in the chest cavity, causing air to be drawn down into the lungs. The negative pressure formed in the initial 100 ms of a breath is directly proportional to the respiratory incentive generated in the respiratory centre of the medulla oblongata. The respiratory incentive reflects, in turn, the body's need for e.g. oxygen. Accordingly, a large respiratory incentive results in a deep breath, e.g. during heavy physical exertion when the body needs a large amount of oxygen. A normal value for the respiratory incentive is about a 2 cmH_2O drop in pressure in the first 100 ms. During expiration, the musculature relaxes, and air is expelled from the lungs.

[0005] In injuries and illness, a patient's ability to breathe may be so compromised that supplementary respiratory assistance must be provided by a breathing apparatus, usually a ventilator. This may also be the case when a patient's ability to breathe is suppressed, e.g. during anaesthesia.

[0006] It should be noted that the term 'patient' in this application refers, in principle, to all creatures which breathe with lungs but to Man and domesticated animals in particular.

[0007] Ventilators are equipped with triggering systems, which induce an inspiration (inspiratory phase) whenever an attempt by the patient to inhale is detected. Triggering systems can be based on the measurement of pressure, the patient then being required to generate a drop in pressure sufficient to trigger the ventilator, or on the measurement of flow, the patient then being required to generate a gas flow sufficient to trigger the ventilator. The gas flow generated naturally depends on the negative pressure the patient is able to produce. Combinations of pressure measurement and flow measurement are also used.

[0008] The ventilator supplies breathing gas at the flow and pressure set by the physician for each patient. For example, the physician sets the apparatus pressure to which the patient is subjected at the end of an expiration (PEEP - Positive End Expiratory Pressure or, less commonly, NEEP - Negative End Expiratory Pressure). PEEP refers to a positive pressure in relation to the surroundings and can therefore range from 0 cmH_2O on up. The physician also selects the ratio between inspiratory duration and expiratory duration.

[0009] In other words, the patient must make some inspiratory effort in order to trigger the ventilator into delivering a flow of gas. If a patient is unable to make this effort, the ventilator must, in principle, exercise complete control over the patient's breathing. Even if this is essential to the survival of many patients, it could simultaneously contribute to a weakening or, at worst, a wasting of the patient's respiratory musculature. This leads, in turn, to prolonged recovery times and a heavier burden on treatment facilities (both in terms of costs and bed occupancy)

[0010] Effective triggering could therefore result in more rapid recovery and weaning off respiratory assistance for the patient. When a magnitude for the respiratory incentive is selected at which a large inspiratory incentive causes more breathing gas to be supplied, respiratory assistance can be better tailored to the patient's needs.

[0011] One problem found here concerns the presence of residual positive pressure inside the lungs. In the present application, this residual positive pressure is designated Auto-PEEP. A plurality of factors can lead to the development of residual positive pressure in the lungs. Some of these factors are physiological, such as flow resistance in the lungs slowing evacuation of some parts of the lungs. Other factors are apparatus-related, such as the ratio between inspiration duration and expiration duration and between respiratory rate and tidal volume.

[0012] Auto-PEEP causes the true pressure gradient the patient needs to overcome in order to trigger the ventilator to exceed the value anticipated at the prevailing ventilator settings. The effort the patient must make increases, and the delivery of breathing gas is delayed.

[0013] Therefore, a more reliable way of determining when the patient starts an inspiration is needed so respiration can be facilitated in the best way possible.

[0014] One objective of the invention is to achieve a method making it possible to determine the patient's true circumstances in relation to her/his inspiratory effort/attempts at inspiration.

[0015] Another objective of the invention is to achieve a method making it possible to determine the patient's anticipated attempts at inspiration.

[0016] Yet another objective of the invention is to achieve a method making possible improved determination of the patient's inspiratory incentive.

[0017] An additional objective of the invention is to achieve a method making possible better determination of the patient's inspiratory effort.

[0018] Yet another objective of the invention is to achieve a breathing apparatus designed for improved detection of the patient's inspiratory effort/attempts at inspiration.

[0019] A method, which resolves all this, is achieved according to the invention with the method steps evident from the characterising part of claim 1.

[0020] Advantageous embodiments of the method are evident from the dependent claims of claim 1.

[0021] A number of advantages and various information can be obtained when the pressure gradient generated by the patient in inspiration and residual positive

pressure in the lungs are determined. Graphic depiction of the determined values can be displayed on a screen on the ventilator or on a separate monitor. When graphic display of true conditions is available, the physician is able to assess the true respiratory effort the patient needs to make as well as the delay in the ventilator's response. The physician can then decide whether the true conditions warrant any changes in the patient's treatment.

[0022] The delay and respiratory effort can also be calculated by first extrapolating the pressure gradient against the level of Auto-PEEP.

[0023] An alternative method that reaches the objectives according to the invention is achieved when the method comprises the method stages evident from the characterising parts of claim 7.

[0024] An advantageous embodiment of the method is evident from the dependent claim of claim 7.

[0025] Determining the patient's expiratory curve, the flow curve in particular, makes it possible to extract information on conditions in the lung from the curve. Any commenced attempt at inspiration in particular will generate a change in the curve. Analysis of this part of the curve in one or a plurality of breaths makes it possible to predict an attempt at inspiration in subsequent breathing cycles. In principle, a real time analysis of the curve can be used for generating a triggering signal when changes in the curve indicate the patient has started an attempt to inhale.

[0026] This can also be advantageously combined with the method described above.

[0027] A breathing apparatus is achieved according to the invention when it is devised as is evident from the characterising part of claim 9.

[0028] Advantageous embodiments of the breathing apparatus are evident from the subordinate claims of claim 9.

[0029] In principle, the breathing apparatus can consist of a conventional ventilator equipped with a determination unit devised to perform one or a plurality of the described methods.

[0030] The methods and breathing apparatus according to the invention will be described below in greater detail, referring to the figures in which

FIG. 1 is a diagram describing a triggering, a triggering delay and a patient's attempt at inspiration;
FIG. 2 shows one way to determine a patient's respiratory incentive;
FIG. 3 is a diagram illustrating a tailored Auto-PEEP and apparatus-PEEP;
FIG. 4 is a diagram showing an expiratory curve; and
FIG. 5 is one embodiment of a breathing apparatus according to the invention.

[0031] The diagram in FIG. 1 shows part of a respiratory curve 2 in relation to Auto-PEEP 4, apparatus-PEEP 6 and a triggering level 8. When a patient starts an inspiration, she/he must first overcome the pressure gradient between Auto-PEEP 4 and apparatus-PEEP 6. The difference in pressure between apparatus-PEEP 6 and the triggering level 8 (the descending flank of the respiratory curve 2) must thereupon also be overcome before the ventilator supplies respiratory assistance (the rising flank of the respiratory curve 2).

[0032] The gap between Auto-PEEP 4 and apparatus-PEEP 6 has several consequences. The time required to overcome this gap causes a needless delay Δt before respiratory assistance is supplied. The area 10 corresponds to the additional breathing effort the patient must make in order to obtain respiratory assistance. Any attempt to determine the respiratory incentive (see FIG. 2 for additional details on this determination) is also performed with a delay greater than the delay Δt. The respiratory incentive can be determined in the initial 100 ms of an inspiration, but the delay Δt can itself last for 200-250 ms. As a result, determination of the respiratory incentive does not take place until after 250-350 ms. It is then by no means certain that the respiratory incentive determined really corresponds to the patient's true respiratory needs.

[0033] FIG. 2 illustrates the procedure for determining the respiratory incentive. The lines for Auto-PEEP 4, apparatus-PEEP 6 and the triggering level 8 are the same as in FIG. 1. The respiratory curve 12 corresponds to the respiratory curve 2 in FIG. 1.

[0034] When the triggering level 8 is reached in a patient's attempt at inhalation, the delivery of respiratory assistance can be delayed for the time t_m, e.g. 100 ms. During this period of time, the patient continues to generate negative pressure in her/his lungs, and this negative pressure (the difference between the triggering level 8 and the triggering level 14), designated ΔP, then constitutes the respiratory incentive. The angle for the determined pressure difference ΔP in relation to the triggering level can be determined and is referred to as the pressure gradient. The intersection with Auto-PEEP 4 can be established by extrapolation, and the delay Δt and inspiratory effort 10 in FIG. 1 can be determined.

[0035] Extrapolation of the pressure gradient is shown as linear in FIG. 2, but as is evident from the above description, the respiratory incentive is not necessarily linear throughout this period of time (which can amount to 300-350 ms). Other, non-linear extrapolations can therefore be used in determining the intersection with Auto-PEEP 4. Extrapolation related to the pressure gradient can also be performed. A large pressure gradient (a big difference in the pressure ΔP during the interval t_m) can be subjected to linear extrapolation, whereas a small pressure gradient can be extrapolated with a function yielding a pressure gradient that increases as Auto-PEEP 4 approaches the extrapolation curve 12A.

[0036] With appropriate adaptation of respiratory assistance, Auto-PEEP and apparatus-PEEP can be made to approach one another, as illustrated in FIG. 3.

FIG. 3 shows Auto-PEEP 4A, apparatus-PEEP 6A and the triggering level 8A with an inspiratory curve 16. FIG. 3 shows that the delay Δt before the patient receives breathing assistance is much shorter than in FIG. 1, and additional inspiratory effort 18 is greatly reduced.

[0037] Adaptation of respiratory assistance can comprise one or a plurality of the following changes.

[0038] Adaptation of apparatus-PEEP to Auto-PEEP, preferably by allowing apparatus-PEEP to be a percentage (e.g. 70-90%) of Auto-PEEP. This result in improved triggering for the patient and reduced inspiratory effort. The patient's breathing is accordingly facilitated, and Auto-PEEP declines. Continuous monitoring of Auto-PEEP and apparatus-PEEP makes possible a successive reduction in both to a lower level.

[0039] An adaptation of the inspiratory and expiratory durations to give the lungs more time to evacuate delivered breathing gas makes it possible to reduce Auto-PEEP. Alternately, the flow curve for delivered breathing gas or tidal volume can be modified to achieve the corresponding effect. Here, modest adaptation may be sufficient to achieve a positive trend, i.e. with a declining Auto-PEEP, thanks to a reduced delay and inspiratory effort.

[0040] FIG. 4 shows an alternative method according to the invention for obtaining essential information related to the patient's attempts at inspiration. The diagram in FIG. 4 shows flow Φ in relation to time t. An expiratory curve 20 designates the way in which breathing gas flows out of the patient's lungs during expiration.

[0041] In principle, the expiratory curve 20 designates the way in which the breathing apparatus registers events during apparatus-related expiration. By definition, expiration does not end for the breathing apparatus until the patient triggers a new breath. As is evident from the above, the patient may already have begun an attempt at inspiration at an earlier point in time. This attempt at inspiration therefore occurs, by definition, at the end of the expiratory phase.

[0042] An enlarged segment 22 of the expiratory curve 20 shows that fluctuations occur in the flow curve. Some of these fluctuations develop as the result of the patient's commenced attempts at inspiration.

[0043] A number of conclusions, preferably based on the corresponding area in two or more respiratory cycles, can be drawn from analysis of this part of the expiratory curve 20. Patient-related fluctuations in particular can then be filtered out.

[0044] They can then be used for 'teaching' the breathing apparatus to identify corresponding variations in subsequent respiratory cycles, such as attempts at inspiration, and trigger breathing assistance before the patient has generated the usual negative pressure and/or change in flow required for triggering.

[0045] These fluctuations can also be used for making 'predictions', i.e. for calculating an anticipated time at which an attempt at inspiration will be made in the next respiratory cycle. This could be helpful by activating the breathing apparatus at the anticipated time so the breathing apparatus delivers a gas flow enabling triggering to occur with greater sensitively than usual.

[0046] FIG. 5 shows one embodiment of a breathing apparatus according to the invention. The breathing apparatus 24 can be connected to a patient 26 and provide her/him with breathing assistance. The breathing apparatus 24 consists of a ventilator 28 which supplies breathing gas, via an inspiratory tube 30 and a patient tube 32, to the patient 26. Expired breathing gas is returned to the ventilator 28 through the patient tube 32 and an expiratory tube 34. The breathing apparatus 24 also comprises a user interface 36 which a physician can use for programming a suitable operating mode and breathing gas parameters for the ventilator 28 with the aid of control knobs 38. Visual information can be shown on a display 40. For example, the ventilator's 28 programmed operating mode can be displayed as well as measured parameters such as flow, pressure, gas composition and the various parameters determined with the above-described methods according to the invention, i.e. Auto-PEEP, apparatus-PEEP, pressure gradient, extrapolation of the pressure gradient, the expiratory curve etc.

[0047] The user interface 36 can be integrated into the ventilator 28, or communicating with it can be by cord, IR, radio waves or some other means. The user interface 36 communicates primarily with a control unit 42 in the ventilator 28. The control unit 42 controls all functions in the ventilator 28 and also collects all measurement values from meters, transducers and sensors in the ventilator 28 (or connected to the ventilator 28).

[0048] Breathing gas, in the form of one or a plurality of gases, is delivered to a first gas connector 46A, a second gas connector 46B and a third gas connector 46C. The flow and pressure of the connected gases (or gas) are regulated in a gas flow generator 44 and mixed into breathing gas in a mixing chamber 48 before being delivered to the patient 26 through an inspiratory tube 30. The pressure of breathing gas in the inspiratory part of the ventilator 28 can be measured by a first manometer 50, and flow can be measured by a first flow meter 52. (In principle, pressure and flow can also be obtained from the gas flow generator 48.)

[0049] Pressure on the expiratory side of the ventilator 28 can be determined by a second manometer 54, and flow can be determined by a second flow meter 56. An expiratory valve 58, controlled by the control unit 42, regulates the outflow of gas, apparatus-PEEP in particular.

[0050] A calculation unit 60 is arranged in the control unit 42. The calculation unit 60 is devised to perform the required signal analyses and calculations required for performing one or a plurality of the methods described above. In particular, the calculation unit 60 determines Auto-PEEP, pressure gradient, extrapolation calculations, delay calculations, inspiratory effort calculations and analysis of expiration curves.

[0051] The control unit 42 can also be modified to determine, from the various determinations the calculation unit 60 can perform, and propose on the display 40 possible changes in ventilator 28 settings. As an alternative, or complement, the control unit 42 can additionally be modified to automatically generate control and triggering signals related to the conditions ascertained by the calculation unit 60. Especially adaptation of the ventilator's 28 operating mode, as discussed above.

[0052] The magnitude of adaptations and the measure(s) that may be appropriate in any particular situation can be regulated in relation to compliance with certain pre-set conditions. Using an artificial neural network (ANN) or corresponding technology the control unit 42 can be successively 'taught' to more reliably identify when a change in the operating mode is necessary and to more reliably propose the most advantageous change in operating mode.

[0053] The breathing apparatus has been described above as a ventilator, but the same arguments also pertain to anaesthetic machines, respirators and other equipment for respiratory assistance.

Claims

1. A method for determining at least one parameter related to a patient's spontaneous attempts at inspiration and/or the patient's respiratory effort in spontaneous attempts at inspiration, **characterised** by the following method steps:

   determining a pressure gradient ($\Delta P/t_m$) in relation to a known apparatus pressure (8) and time (t_m), said pressure gradient ($\Delta P/t_m$) being generated by the patient at inspiration;
   determining a residual positive pressure (4) in the patient's lungs (Auto-PEEP); and
   generating a signal.

2. The method according to claim 1, **characterised** in that the output signal consists of information corresponding to the determined pressure gradient ($\Delta P/t_m$) and the determined residual positive pressure (4).

3. The method according to claim 1 or 2, **characterised** in that the determined pressure gradient ($\Delta P/t_m$) is extrapolated with consideration taken to the determined residual positive pressure (4).

4. The method according to claim 3, **characterised** in that the delay (Δt) between the extrapolated pressure gradient's (12A) intersections with apparatus pressure (6) and residual positive pressure (4) respectively are determined, the output signal then containing information on the delay (Δt).

5. The method according to claims 3 or 4, **characterised** in that the area (10) between the extrapolated pressure gradient (12A) and residual positive pressure (4) is determined, the output signal then containing information on the area (10).

6. The method according to any of the above claims, **characterised** in that the output signal is shown on a display (40).

7. A method for determining at least one parameter related to a patient's spontaneous attempts at inspiration and/or the patient's respiratory effort in spontaneous attempts at inspiration, **characterised** by the following method steps:

   determining the expiratory curve (20) for one breathing cycle; and
   extracting signal components, related to an attempt at inspiration by the patient, from the determined expiratory curve.

8. The method according to claim 7, **characterised** in that an anticipated start for inspiration in the next attempt at inspiration is determined, and the method according to any of claims 1-6 is performed at the anticipated time of the patient's next attempt at inspiration.

9. A breathing apparatus (24), devised for connection to a patient (26), for providing breathing assistance, preferably for providing a patient (26), breathing spontaneously in whole or part, with breathing assistance, said breathing apparatus (24) comprising a gas flow generator (44) for generating gas flows, pressure meters (50, 54), flow meters (52, 56) and a control unit (42) devised to detect attempts to inspire by the patient (26) and control the gas flow generator (44), **characterised** in that the control unit (42) comprises a calculation unit (60) devised to carry out the method set forth in any of claims 1-8.

10. The breathing apparatus according to claim 9, **characterised** in that the calculation unit (60) is devised to carry out the method set forth in any of claims 4-5, the control unit (42) compares the parameter with a predetermined normal value range and the control unit (42) causes the gas flow unit (44) to generate an end expiratory apparatus pressure (apparatus-PEEP, 6; 6A), consisting of a predetermined percentage of the determined residual positive pressure (Auto-PEEP, 4; 4A), if the parameter deviates from the normal value range.

11. The breathing apparatus according to claim 9, **characterised** in that the calculation unit (60) is devised to carry out the method set forth in any of claims 4-5, the control unit (42) compares the

parameter with a predetermined normal value range and the control unit (42) calculates a change in one or more of the respiratory assistance parameters inspiration duration, expiration duration, flow and tidal volume if the parameter deviates from the normal value range.

12. The breathing apparatus according to claim 9, **characterised** in that the calculation unit (60) is devised to carry out the method set forth in claim 8, and the control unit (42) causes the gas flow generator to generate a flow of gas, at the anticipated start of inspiration, to facilitate detection of spontaneous attempts at inspiration at the time inspiration is expected to start.

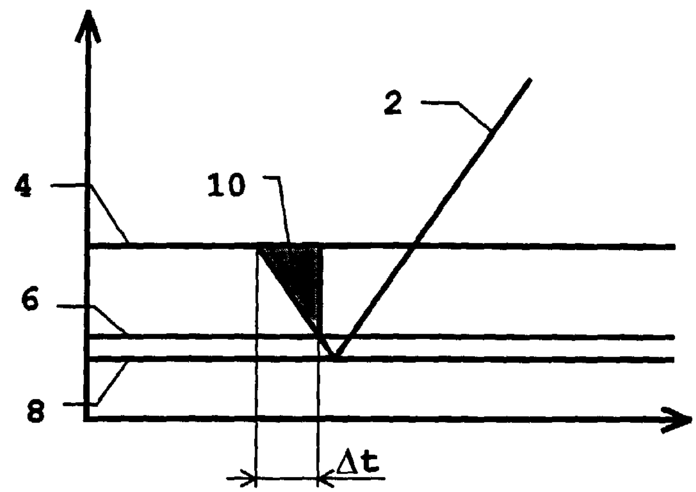

FIG. 1

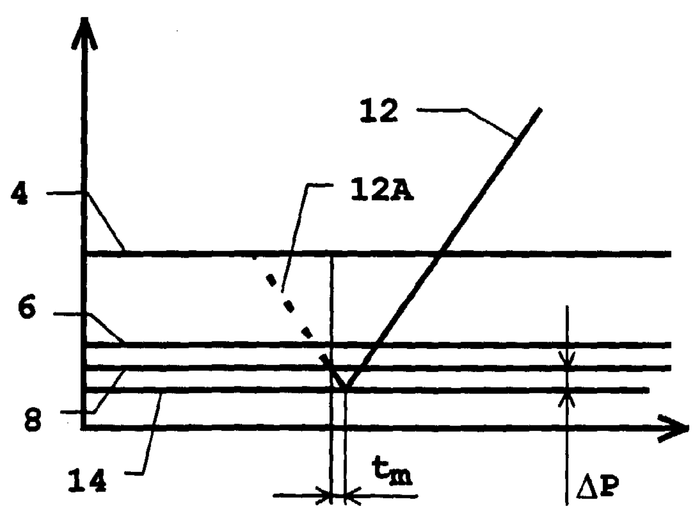

FIG. 2

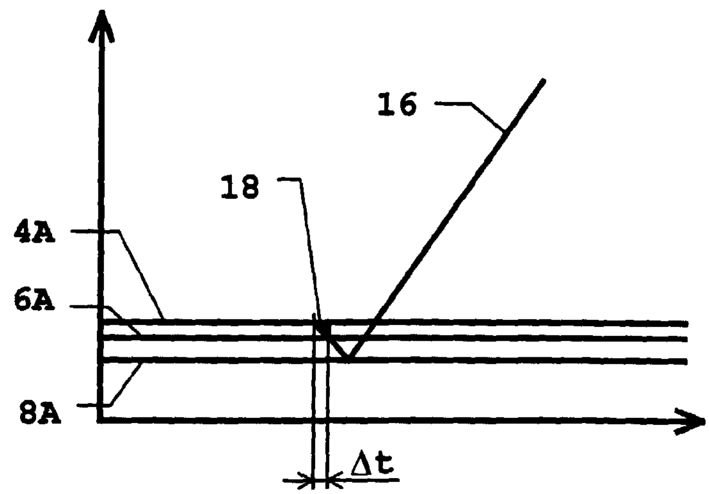

FIG. 3

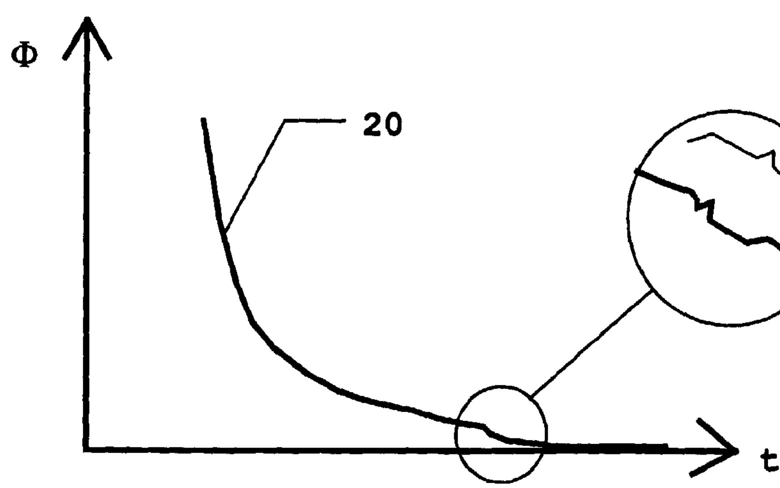

FIG. 4

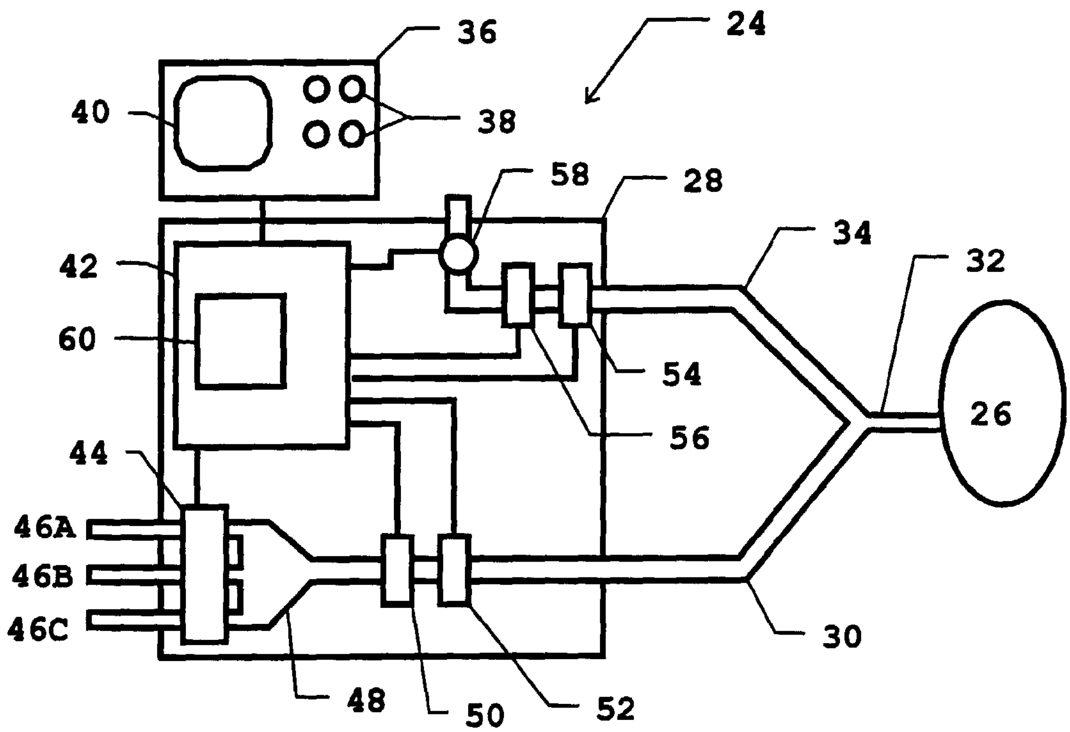

FIG. 5

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EUROPEAN SEARCH REPORT

Application Number
EP 99 10 4394.4

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
Y	EP 0821976 A1 (SIEMENS-ELEMA AB), 4 February 1998 (04.02.98) * figures 1,2, claim 1 * --	1,7,9	A61M 16/00
Y	EP 0745403 A1 (LACHMANN, B.), 4 December 1996 (04.12.96) * figure 1, claim 12 * --	1,7,9	
A	EP 0776672 A1 (SIEMENS-ELEMA AB), 4 June 1997 (04.06.97) * figure 1, claim 1 * --	1-12	
A	EP 0811394 A1 (SIEMENS AKTIENGESELLSCHAFT), 10 December 1997 (10.12.97) * figures 1,2, claim 1 * -----	1-12	TECHNICAL FIELDS SEARCHED (Int. Cl.6) A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	11 August 1999	JONI SAYELER

CATEGORY OF CITED DOCUMENTS

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0821976 A1	04/02/98	JP 10071205 A	17/03/98
		SE 9602913 D	00/00/00
		US 5878744 A	09/03/99
EP 0745403 A1	04/12/96	JP 9000632 A	07/01/97
		SE 9502031 D	00/00/00
		US 5660170 A	26/08/97
EP 0776672 A1	04/06/97	JP 9173456 A	08/07/97
		SE 504285 C	23/12/96
		SE 9504312 A	23/12/96
EP 0811394 A1	10/12/97	JP 10052494 A	24/02/98
		SE 9602199 D	00/00/00

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